



CMS-3368-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 424, 488, and 493

[CMS-3368-P]

RIN 0938-AT83

Medicare Program; Accrediting Organizations- Changes to Change of Ownership

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would add requirements and a specified process to address changes of ownership as they relate to the sale, transfer, and/or purchase of assets of Accrediting Organizations (AOs) with the Centers for Medicare & Medicaid Services (CMS)-approved accreditation programs. This change is intended to provide CMS the ability to receive notice when an AO is contemplating undergoing or negotiating a change of ownership and the ability to review the AO's capability to perform its tasks after a change of ownership has occurred, in order to insure the ongoing effectiveness of the approved accreditation program(s) and to minimize risk to patient safety.

DATES: *Comments:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, refer to file code CMS-3368-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the

following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **<http://www.regulations.gov>**. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3368-P,
P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3368-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Monda Shaver, 410-786-3410.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

I. Background

Medicare-certified providers and suppliers participate in the Medicare program by entering into a provider agreement with the Medicare program. Medicare-certified providers and suppliers include hospitals, skilled nursing facilities (SNFs), home health agencies (HHAs), hospice programs, rural health clinics (RHCs), critical access hospitals (CAHs), comprehensive outpatient rehabilitation facilities (CORFs), laboratories, clinics, rehabilitation agencies, public health agencies, End Stage Renal Disease (ESRD) dialysis facilities and ambulatory surgical centers (ASCs). To participate in the Medicare program, Medicare-certified providers and suppliers of health care services must among other things, be substantially in compliance with specified statutory requirements of the Social Security Act (the Act), as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (the Secretary). These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for SNFs, conditions for coverage (CfCs) for ASCs and other suppliers, and conditions for certification for RHCs. A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its Medicare provider agreement terminated.

Section 1865(a) of the Act allows most types of Medicare-certified providers and suppliers to demonstrate compliance with the applicable health and safety requirements through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program of a national accreditation body, known as an Accrediting Organization (AO). This is referred to as “deemed” accreditation, because, if an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier which is accredited by that AO’s CMS-approved accreditation program is deemed by CMS as complying with the applicable Medicare conditions or requirements.

The CMS is responsible for providing continued oversight of national AOs’ Medicare accreditation programs to ensure that providers or suppliers accredited by the AO meet the required quality and patient safety standards. We must ensure that the AOs have formalized procedures to determine whether the healthcare facilities deemed under their accreditation programs meet the AO’s accreditation standards (which must meet or exceed the applicable Medicare program requirements). CMS is also responsible for ensuring that the AO’s accreditation standards and practices for surveying providers and suppliers meet or exceed CMS’s standards and practices for granting approval.

Additionally, while accreditation by an AO is generally voluntary on the part of the Medicare-certified providers or suppliers, accreditation is mandated by statute for five supplier-types in order to receive payment from Medicare for the services furnished to Medicare beneficiaries. These five supplier types are Advanced Diagnostic Imaging (ADI) suppliers, Home Infusion Therapy (HIT) suppliers, Diabetic Self-Management Training (DSMT) entities, Durable Medical Equipment suppliers, suppliers of Prosthetics, Orthotics, and Supplies (DMEPOS), and clinical laboratories. We describe these providers and suppliers as “non-

certified” because they are enrolled in the Medicare program but are not eligible to become Medicare-certified by entering into a participation agreement with Medicare.

These proposed provisions would affect all of the AOs that accredit providers and suppliers, both those that are enrolled in the Medicare program, and those that enter into a participation agreement with Medicare. We believe that a change of ownership could occur with an AO that accredits either category of providers or suppliers.

Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed 6 years (See 42 CFR 488.5(e)(2)(i)). The AO must also reapply for renewed CMS approval of an accreditation program before the date its existing approval period expires. This allows CMS to continue to ensure that accreditation provided by these AOs continue to indicate that the providers or suppliers accredited are meeting or exceeding Medicare standards. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

We have an established process for the change of ownership of Medicare-certified providers and suppliers set forth at § 489.18 and in Chapter 100-07 of the State Operations Manual (SOM). Although the existing provider and supplier change of ownership process does not apply to the sale and transfer of AOs, we believe that it serves as an appropriate model for what we are proposing to require for changes of ownership of AOs.

Section 489.18 defines what constitutes a change of ownership, the required notice from the current provider, the disposition of the current provider agreement and the conditions that apply to the provider agreement once it is assigned or transferred to the new owner. The Medicare regulations at § 489.18, as well as the CMS State Operations Manual (CMS Pub. 100-07), outline processes concerning how a change of ownership of a provider or supplier affects

Medicare participation, such as how a provider agreement is automatically assigned to a new owner unless the new owner rejects assignment of the provider agreement. A change of ownership takes place when the responsible legal entity has changed and typically occurs when a Medicare provider has been purchased (or leased) by another organization. This section specifically defines what constitutes a change of ownership for purposes of Medicare, the effect on the provider agreement, and requires a provider that is contemplating or negotiating a change of ownership to notify CMS (See § 489.18(b)). In general, and with certain limited exceptions, under this existing process if a facility's new owner accepts the assignment of the provider agreement and provider number (also known as a CMS Certification Number (CCN)), the provider agreement remains intact, the new owner retains all the benefits and liabilities of that agreement, and the provider's Medicare participation continues without interruption. If the purchaser (or lessee) elects not to accept automatic assignment or transfer of the provider agreement, then that rejection is considered to be a voluntary termination of the existing provider agreement. Therefore, the purchaser or lessee is considered a new applicant and must request initial certification as a new provider and obtain a new provider agreement. It is important to clarify that CMS does not approve the actual business transaction between entities that result in the change of the responsible legal entity. Instead, CMS' role when provider ownership changes is to ensure that a new owner who accepts the automatic assignment of the existing provider agreement (a change of ownership) is eligible for Medicare participation. If so, we continue to treat the provider as the same entity, with only the owner having changed. Section 489.18(d) provides that where there is a change of ownership (defined as automatic assignment of the provider agreement at § 489.18(c)), the provider agreement under the new owner is subject to all applicable statutes and regulations, and to the terms and conditions under which it was originally

issued. This includes successor liability for Medicare overpayments and penalties.

If the new owner rejects automatic assignment of the provider agreement, then it must seek initial Medicare enrollment and certification for the facility, which may take several months. A new owner who rejects automatic assignment cannot receive payment for any services it may provide for Medicare beneficiaries between the date it acquires the facility and the date we determine that it meets all Medicare requirements at § 489.13.

Currently, the regulations governing AOs do not include a process for notifying CMS of pending changes of ownership or other procedures, which would allow CMS to review information about the proposed transfer of ownership of accreditation program(s) and the authority for CMS to approve or deny the transfer of the existing CMS approval for the accreditation program(s) to be transferred. Under our current regulations, CMS does not typically become aware of a sale or transfer until an AO applies for renewal of CMS approval of its accreditation program(s) or if voluntarily notified by the AO (although CMS always retains the right to conduct comparability or validation surveys in accordance with § 488.8). Thus, we do not believe that we currently have the explicit regulatory authority to prospectively review and approve or deny the transfer of the existing Medicare-approval of accreditation programs being transferred in a change of ownership transaction to ensure that after such transfer, the AO could continue to ensure that the entities it accredits meet or exceed CMS requirements in order to be granted CMS approval of its program(s).

We believe that the current situation, whereby a change in ownership of CMS-approved accreditation programs may occur without notice to CMS, which does not provide an opportunity for CMS to review and approve or deny the transfer of the existing CMS-approval of the accreditation programs to be transferred. We believe that this scenario must be addressed so that

we may assure Medicare beneficiaries that the standards and conditions for surveying facilities will continue to be met by the accreditation programs that are transferred under new ownership. We also believe it is possible that the AO, after a change of ownership transaction, may not be viable or equipped to accredit facilities under the transferred CMS approved CMS accreditation programs, due to the new owner's inability to enforce the health and safety requirements of CMS. Without the authority to require AOs to provide CMS with notice when they are contemplating or negotiating a change of ownership, and the authority to review the ability of the prospective new owner's capability to perform the required accreditation tasks, after a change of ownership, CMS is unable to confirm the ongoing effectiveness of the transferred CMS-approved accreditation program(s).

II. Provisions of the Proposed Regulations

Although the existing provider and supplier change of ownership process outlined above (§ 489.18) does not apply to the sale and transfer of AOs, we have used it as a model for this proposal because stakeholders are familiar with it and we are hopeful to reduce their burden. In addition to the current AO regulations for application and reapplication procedures for national AOs (§ 488.5), we are proposing to add notification and approval requirements in the event there is an anticipated change of ownership of an AO. The proposed procedure would enable CMS to determine whether the new AO would be able to meet the appropriate accreditation requirements to be awarded deeming authority by CMS for the new or transferred CMS-approved accreditation programs. This means that we would make a decision as to whether to allow the existing Medicare-approval for the accreditation programs involved in the change of ownership transaction to be transferred to the new owner/transferee.

As noted above, we currently have no regulatory authority to review and approve the transfer of the existing Medicare approval of the accreditation programs undergoing a change of ownership to ensure that immediately after the transfer, the purchaser or transferee ensures that the providers and suppliers it accredits continue to meet or exceed CMS accreditation and survey requirements. Additionally, we consider AOs which have ceased doing business to have voluntarily terminated their Medicare approval(s); therefore, if another entity subsequently purchased the property of the defunct AO with the intent of operating as an AO, we would require that entity to begin the AO approval process from the beginning. In most cases, CMS would be able to determine an AO's cessation of business either through—(1) a change in their accreditation name on the required reapplication documents for approval of their accrediting programs; (2) notification of cessation of business, or notification that the entity approved for deeming authority (published in the **Federal Register**) is no longer in control or operation of the AO; or (3) a validation survey process.

We propose at § 488.5 to add a new paragraph (f) that would set out the requirements and processes for CMS' review and approval of the transfer of the existing CMS-approval for the accreditation program(s) to be transferred in the change of ownership event. We propose at § 488.5(f)(1)(i), that any CMS-approved AOs negotiating or engaging in a change of ownership transaction must provide notice of this change of ownership transaction to CMS. At proposed § 488.5(f)(1)(ii) and (iii), we would require that this notice be provided to CMS in writing no less than 90 days prior to the effective date of the transfer of ownership. This notice requirement would allow CMS to perform an evaluation of whether the AO, under the new ownership, would (1) be viable or equipped to accredit facilities under its existing CMS approval; (2) be able to

enforce the health and safety requirements of CMS for that program; (3) operate effectively; and (4) continue to meet or exceed the Medicare standards.

We would further require the prospective new owner or transferee to submit certain information to CMS for review in support of their request for transfer of the existing CMS-approval of the CMS-approved accreditation programs to be transferred. We propose at § 488.5(f)(2)(iii), to require the prospective new owner or transferee to submit the following information: (1) the name and address of the legal entity that would be the owner of the new AO after the transfer is completed; (2) the three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities; (3) a transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner. Section 488.5(f)(2)(iii)(C) would require that the AO's transition plan include the following information: (1) changes to management and governance structures including current and proposed organizational charts; (2) a list of the CMS-approved accreditation programs that will be transferred to the purchaser/buyer/transferee; (3) Employee changes, if applicable; (4) anticipated timelines for action; (5) plans for notification to employees; and (6) any other relevant information that CMS finds necessary.

It is important in the process of a change of ownership that the purchaser or transferee and seller develop a transition plan that allows for details to be considered and addressed, which may be relevant to the transfer of the CMS approved accreditation program that could impact the health and safety of patients. Transition plans may include but are not limited to management structures, organizational charts which reflect existing and new positions or departments, governance, employee changes, and any substantive changes to the AOs operations or

accreditation programs associated with the sale or transfer. In the event the transition plans provided to CMS by the purchaser or transferee were determined by CMS to be inadequate, we could request revisions to the plans or deny the transfer of the existing CMS-approval for the accreditation program(s), which are part of the change of ownership transaction, as we believe these plans directly impact patient safety within facilities. In addition, we believe that the review of this information would allow CMS to ensure an AO is capable of continuing to provide safe and effective accreditation services to those healthcare settings they serve.

We propose at § 488.5(f)(3)(i), to require the purchaser or transferee to provide a written acknowledgement, which states that if CMS approve the transfer of the existing CMS-approval of the accreditation programs that are part of the change of ownership transaction, the new owner will become managerially, legally, and financially responsible for the operations of all CMS-approved accreditation programs being transferred. This means that upon our approval of the transfer of the existing CMS-approval for the accreditation programs being transferred, and upon the finalization of the change of ownership transaction, the purchaser or transferee would be completely responsible for the management of the business operations of the AO, including, but not limited to the day to day business operations, the survey and accreditation processes, the oversight of accredited providers and suppliers, the handling of complaints regarding accredited suppliers, and the compliance with all CMS requirements. This acknowledgement would ensure that the purchaser or transferee knows that they will be accountable for any oversight concerns from the date CMS grants approval of the transfer of the program and deeming authority and after the change of ownership has taken affect, in accordance with CMS' policy of successor liability.

Furthermore, we propose at § 488.5(f)(3)(ii), to require the purchaser or transferee to provide CMS with a written acknowledgment stating that they agree to operate the transferred CMS-approved accreditation program(s) under all the terms and conditions found at §§ 488.5 through 488.9.

We propose at § 488.5(f)(3)(iii), that the purchaser or transferee would be required to provide a written acknowledgement that they would not operate the accreditation program(s) it acquired as a CMS-approved accreditation program(s) until they received from CMS a notice of approval of the transfer of the CMS approved accreditation programs.

We propose at § 488.5(f)(4)(i), that the parties to the change of ownership would be required to notify the providers and suppliers affected by the change of ownership within 15 calendar days after being notified of CMS's approval of the transfer to the existing CMS-approval for the accreditation program(s) being transferred. Additionally, we propose at § 488.5(f)(4)(ii), that if the AO or accreditation program(s) being acquired were under a performance review or under probationary status at the time the change of ownership notice was submitted, the purchaser or transferee would have to acknowledge such status in writing. We believe that the purchaser or transferee must understand that when the CMS-approved accreditation program(s) are transferred under the change of ownership, all current terms and conditions, and responsibilities are included in the transfer.

We propose at § 488.5(f)(5), that we would publish a notice in the **Federal Register**, which would acknowledge the transfer of the CMS-approved accreditation program(s) due to the change of ownership event and state that the accreditation program(s) to be transferred, which were previously approved by CMS will retain this CMS-approval under the new ownership. This notice is only intended to inform the public of the ownership change; therefore, the notice

would not solicit public comments. This section further provides that we would not publish this notice after CMS has issued approval for the transfer, without first receiving written confirmation that the change of ownership has taken place. We believe this would avoid potential issues in which CMS may publish a notice in the **Federal Register** based solely on its approval, without having confirmation of the completed transaction.

We propose at § 488.5(f)(6), that in the event CMS did not approve the transfer of the existing CMS approval for the accreditation programs subject to the change of ownership event, CMS would notify all parties to the change of ownership transaction in writing. This notice would be sent to the relevant parties at the existing AO and the prospective transferee.

We propose at § 488.5(f)(7)(i), in the event CMS was not made aware of a change of ownership transaction, or did not approve the transfer of the existing CMS approval for the accreditation program(s) subject to transfer through a change of ownership event, the subject AO would be able to continue operating under the existing CMS approval for its accreditation programs if the change of ownership transaction was not completed. The exception to this proposal would be in the event that our review of the un-finalized change of ownership transaction revealed performance and/or compliance issues that were previously unknown to CMS with the AO that was the subject of the un-finalized transfer.

We also propose at § 488.5(f)(7)(ii), that CMS would be able to withdraw the CMS approval of an AO's accreditation programs in accordance with § 488.8(c)(3)(ii) and (iii), if a change of ownership transaction was completed without notice to CMS or without the approval of CMS to transfer the existing CMS approval for the accreditation program(s) to the new owner.

We propose at § 488.5(f)(8), that in the event parties completed the change of ownership transaction, notwithstanding CMS disapproval of the request to transfer the existing CMS

approval for the accreditation programs to the new ownership, and the purchaser or transferee attempted to operate the transferred accreditation programs under the CMS-approval granted to the previous owner of the accreditation program(s), for which the transfer was disapproved, CMS would withdraw the approval of the accreditation programs in accordance with the procedures set out at § 488.8(c)(3)(ii) and (iii).

We propose at § 488.5(f)(9), that, in accordance with § 488.8(g), if CMS withdrew the existing approval of transferred accreditation program(s) because a change of ownership transaction was completed without notice to or the approval of CMS, an affected Medicare-certified provider's or supplier's deemed status would continue in effect for 180 calendar days after the removal of the existing CMS accreditation approval if the provider or supplier took the steps stated in § 488.8(g). First, the Medicare-certified provider or supplier would be required to submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**. Second, the Medicare-certified provider or supplier would be required to provide written notice to the SA stating that it has submitted an application for accreditation under another CMS-approved accreditation program within the 60-calendar day timeframe specified in § 488.8(g). Failure to comply with the timeframe requirements specified in § 488.8(g) would place the affected Medicare-certified provider or supplier under the SA's authority for continued participation in Medicare and on-going monitoring. The intent of proposed § 488.5(f)(9) is to protect Medicare-certified providers and suppliers that have been accredited by an AO that received the accreditation program(s) in a change of ownership transaction that was completed without notice to CMS or without receiving the approval of CMS for the transfer of the existing CMS approval for the accreditation program(s) transferred. It is necessary to provide this protection because, if

CMS were to withdraw approval for the improperly transferred accreditation program(s) the providers and suppliers accredited by the affected AO would be left with non-CMS approved accreditation.

However, the provisions of § 488.8(g) would not apply to non-certified providers and suppliers, because the statute does not authorize SAs to engage in oversight of these types of providers and suppliers. Therefore, we propose at § 488.5(f)(10) that if CMS withdrew the existing approval of transferred non-certified accreditation program(s) because a change of ownership transaction was completed without notice to or the approval of CMS, an affected non-certified provider's or supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval if the non-certified provider or supplier submitted an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register** and provided written notice of such application to the CMS within such timeframe. Failure to comply with the timeframe requirements would result in a CMS determination that the provider or supplier was no longer accredited.

For non-certified suppliers such as ADI and DSMT suppliers, CMS-approved accreditation is required as a condition for receipt of CMS reimbursement for the services furnished to Medicare beneficiaries. If these suppliers were suddenly left without CMS-approved accreditation they would have to seek new accreditation from a CMS-approved AO. We estimate that it would take no less than 6 to 9 months for these suppliers to complete the reaccreditation process and obtain new CMS-approved accreditation. We are concerned that during the time that these suppliers were undergoing the reaccreditation process, they would not be able to receive reimbursement from Medicare for any services furnished to Medicare

beneficiaries. For many of these suppliers, Medicare beneficiaries make up a large portion of their client population and provides a large source of revenue for them. Therefore, these suppliers are likely to suffer significant hardship if left without CMS-approved accreditation for a 6 to 9 month period. Also, if these suppliers were not able to provide services to Medicare beneficiaries for an extended period of time, it may create access to care issue for Medicare beneficiaries for the services provided by these suppliers. For this reason, CMS will recognize an accreditation for a 1 year period after **Federal Register** notification that CMS's approval of the non-certified provider or supplier's accreditation organization is being withdrawn.

Because we propose to add the same requirements for ADI, HIT, DSMT, and DMEPOS suppliers, and clinical laboratories, we would add cross references to the provisions in § 488.5(f) for these suppliers so that they would be subject to the same proposed requirements for a change of ownership. Specifically, for DSMT suppliers at § 410.142, we propose to add a new paragraph (k); for ADI suppliers at § 414.68, we propose to add a new paragraph (j); for DMEPOS at § 424.58, we propose to add a new paragraph (f); for HIT suppliers at § 488.1030, we propose to add new paragraph (g); and for laboratories at § 493.553, we propose to add a new paragraph (e).

III. Solicitation of Comments

We are soliciting public comments related to our proposed regulatory requirements, which would govern of the transfer of the existing CMS approval for accreditation programs when there is a change of ownership event of an AO, and more specifically, the requirement for the proposed new owner or transferee to submit an applications to CMS with documentation, which shows that the CMS-approved transferred accreditation programs will continue to perform its tasks safely and effectively after a

change in ownership has occurred to insure the ongoing effectiveness of the approved accreditation program(s) and to minimize risk to patient safety.

While we are soliciting comments on the general provision of requiring an application to be filed with CMS, we are specifically seeking comments on the following areas:

- Documentation Requirements: Financial statements, a transition plan and other relevant information as deemed necessary.
- Written Acknowledgements: Requirement for AOs to provide written acknowledgement that it understands the financial and legal responsibilities involved with the change of ownership process.

We are also requesting that stakeholders provide us with comments on additional information they may believe to be critical to submit to CMS for a change of ownership of AOs. We welcome any feedback received that is related to the text of this proposed rule and will take the comments under consideration for final rulemaking.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurse	29-1141	\$35.36	\$70.72
Medical or Health Services Manager	11-9111	\$53.69	\$107.38

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

1. Documentation Requirements:

At § 488.5(f)(1), we propose that the AO that is the subject of the transaction provide notice to CMS that it intends to request approval for a change of ownership. This initial notice would be minimal such as a coversheet, email, or any type of formal notice and would be included in the additional documentation requirements of § 488.5(f)(2).

At § 488.5(f)(2)(i) and (ii), we propose that the prospective purchaser or transferee provide three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities. Additionally, we would require the name and address of the legal entity that would be the owner of the new AO. We believe that this information is documentation that would be easily accessible and require minimal time to gather and submit. Therefore, we have considered that the cost burden for the AO to submit the financial statements and other information deemed necessary by CMS would be approximately \$70.72. We believe it is likely that the AOs use a registered nurse to gather information; therefore, according to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>) and we estimate the time to gather the financial statements would not exceed one hour. The wage rate would be doubled to include overhead and fringe benefits. The AO would incur a cost burden in the amount of \$70.72 for the preparation of the response to CMS (1 hour x \$70.72)

At § 488.5(f)(2)(iii), we also propose to require the prospective purchaser or transferee to submit a transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner. While most existing AOs engaged in business transactions such as a change of ownership would have already developed a transition plan as proposed under Section II of this proposed rule, this process will be more time consuming. The development of

a transition plan would take approximately 45 hours of time to gather, obtain, or prepare all documentation for submission. We estimate that the AO would have a total of two staff work on transition plan and that the staff would likely be clinicians such as registered nurse or medical or health services manager, as they currently serve in roles for submission of general accrediting approvals. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>) and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>). Therefore, we estimate that the AOs would incur wages for 45 hours of time by a registered nurse and wages for 45 hours of time by a medical or health services manager in the amount of \$8,014 (45 hours x \$70.72 per hour = \$3,182) + (45 hours x \$107.38 = \$4,832 per hour) +

2. Written Acknowledgements

At § 488.5(f)(3), we propose the purchasing AO to provide several written acknowledgements. At § 488.5(f)(3)(i), we are proposing to require the purchaser or transferee to provide written acknowledgement that it understands the financial and legal responsibilities involved with the change of ownership process. We believe this written acknowledgement would be developed by a health services manager, as they currently serve in roles for submission of general accrediting approvals. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>) and we believe this proposed written notice would not exceed 1 hour to develop; therefore, the burden associated would be \$70.72 (\$53.69 x 1 hour x 2 to include overhead and fringe benefits).

At § 488.5(f)(3)(ii), we propose to require the purchasing AO to provide written acknowledgement that it agrees to operate the new AO as defined by CMS' standards under §§ 488.5 and 488.9, as well as include acknowledgements on any program reviews or probationary terms. This would be a minimal cost burden as we are not defining a specific format for the written acknowledgement. Therefore, according to the U.S. Bureau of Labor Statistics, the mean hourly wage for a and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>) and we believe this proposed written notice would not exceed 1 hour to develop, therefore the burden associated would be \$70.72 (\$53.69 x 1 hour x 2 to include overhead and fringe benefits).

At § 488.5(f)(3)(iii), we are proposing to require the purchasing AO to provide written acknowledgement that would not operate the accreditation program until it received a notice of approval of the transfer of the CMS approved accreditation program from CMS. Given this

requirement is minimal and the purchasing AO is already required to include a written acknowledgment as outlined at proposed § 488.5(f)(3)(ii), it is likely that this written notice would include both acknowledgements; therefore, we would include this in the hour of burden and cost described under § 488.5(f)(3)(ii) above.

At § 488.5(f)(5), we propose to require the purchasing AO to provide documentation within 15 days after the sale confirming the change of ownership. Given that this would be a standard business practice or documentation that would generally be required to confirm the sale outside of these proposed requirements, this burden to provide proof of sale would be minimal. This would solely require the purchasing AO to provide a copy; therefore, we estimate the cost to be \$53.39. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>) and this proposed written notice would only require 30 minutes to provide a copy to CMS via electronic methods (email); therefore, the burden associated would be \$53.69 ($\$26.84 \times 0.5 \text{ hours} \times 2$ to include overhead and fringe benefits).

Finally, there is potential for AOs to incur a cost burden for the wages of the AO staff that are involved with reviewing CMS' additional requests for information and the preparation of the written acknowledgements. The AO staff that would review information requested by CMS regarding the change of ownership would be a clinician such as registered nurse, as is generally the case in AO applications seeking deeming authority. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). In order to include overhead and fringe

benefits the wage is doubled. Therefore, the AO would incur a cost burden in the amount of \$70.72 for the preparation of the response to CMS (1 hour x \$70.72).

We want to emphasize that these anticipated costs and burdens are only subject to those AOs seeking a change of ownership. To date, there has only been one change of ownership request of an AO in over 20 years or more, therefore this occurrence is rare.

The requirements and burden will be submitted to OMB under (OMB control number 0938-New).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget. We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We do not

expect this rule to reach that threshold, and thus it is neither economically significant under EO 12866, nor a major rule under the Congressional Review Act.

Burden for Change of Ownership among Accrediting Organizations

The AOs which seek to sell or transfer or purchase another AO and undergo a change of ownership would incur time and cost burdens associated with the preparation of the information they submit to CMS to request approval of their new accreditation program under the change of ownership. This would include the preparation, gathering or obtaining of all the documentation required in proposed § 488.5(f).

While we recognize that most existing AOs would likely be familiar and have majority of the documentation CMS is requesting at proposed § 488.5(f), we believe that due to the need for the selling or transferring and purchasing AOs to submit documentation for both entities, that this would take approximately 2 hours of time to gather, obtain or prepare all documentation required by proposed § 488.5(f). It would take approximately 2 hours as the AOs have previously submitted an application to CMS requesting approval of their accreditation program; therefore, would already be familiar with the application process and requirements and have the majority of the documents requested under the change of ownership, readily available.

The AOs (selling or transferring and purchasing) would incur costs associated with the preparation and submission of the requested documents, development of the written acknowledgement letters, and submission of the documents. The AO would incur costs for the wages of all AO staff that work on the preparation of the change of ownership application. We estimate that the AO would have a total of two staff work on the preparation of the application. We believe that the AO staff that prepare the application would likely be clinicians such as registered nurse or medical or health services manager, as they currently serve in roles for

submission of general accrediting approvals. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>) and the mean hourly wage for a medical or health services manager is \$53.69 (<https://www.bls.gov/oes/current/oes119111.htm>). Therefore, we estimate that the AOs would incur wages for 2 hours of time by a registered nurse and wages for 2 hours of time by a medical or health services manager in the amount of \$356.20 (2 hours x \$35.36 per hour = \$70.72) + (2 hours x \$53.69 = \$107.38) + (\$178.10 for fringe benefits and overhead, estimated at 100% of the hourly wage).

Furthermore, under proposed § 488.5(e)(8), we would require the AOs to provide additional information as requested by CMS to ensure the continuity of oversight for facilities currently accredited. Therefore, there is potential for AOs to incur a cost burden for the wages of the AO staff that are involved with reviewing CMS's additional requests for information and the preparation of the documents and program standards. The AO staff that would review information requested by CMS regarding the change of ownership would be a clinician such as registered nurse, as is generally the case in AO applications seeking deeming authority. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is \$35.36 (<https://www.bls.gov/oes/current/oes291141.htm>). Therefore, the AO would incur a cost burden in the amount of \$70.72 for the preparation of the response to CMS (1 hour x \$35.36 per hour = \$35.36) + (\$35.36 for fringe benefits and overhead).

We want to emphasize that these anticipated costs and burdens are only subject to those AOs seeking a change of ownership. To date, there has only been one change of ownership request of an AO in over 20 years or more, therefore this occurrence is rare in its entirety.

As these change of ownerships are rare among AOs, we do not believe that the burden would be substantial. We are soliciting comments, specifically from stakeholders and AOs and request AOs to submit their comments to include a breakdown of potential costs they would estimate for this to be completed.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an initial regulatory flexibility analysis because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in

any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” OMB’s interim guidance, issued on April 5, 2017, <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf>, explains that for Fiscal Year 2017 the above requirements only apply to each new “significant regulatory action that imposes costs.” It has been determined that this proposed rule is not a “significant regulatory action” and thus does not trigger the above requirements of Executive Order 13771.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, Supplementary Medical Insurance (SMI) Benefits, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases,

Medicare, Reporting and recordkeeping requirements

42 CFR Part 424

Conditions for Medicare Payment, Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements, Survey, Certification, and Enforcement Procedures

42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services propose to amend 42 CFR chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

2. Section 410.142 is amended by adding paragraph (k) to read as follows:

§ 410.142 CMS process for approving national accreditation organizations.

* * * * *

(k) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f) of this chapter.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

3. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

4. Section 414.68 is amended by adding paragraph (j) to read as follows:

§414.68 Imaging accreditation.

* * * * *

(j) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership are subject to the requirements set out at § 488.5(f) of this chapter.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

5. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

6. Section 424.58 is amended by adding paragraph (f) to read as follows:

§424.58 Accreditation.

* * * * *

(f) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership are subject to the requirements outlined under § 488.5(f) of this chapter.

PART 488 SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

7. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C 1302; and 1395hh.

8. Section 488.5 is amended by adding paragraph (f) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

* * *

(f) *Change of ownership. What Constitutes Change of Ownership.* A description of what could constitute a change of ownership with respect to a national accrediting organization are those activities described in § 489.18(a)(1) through (3) of this chapter.

(1) *Notice to CMS.* Any CMS-approved accrediting organization that is contemplating or negotiating a change of ownership for must notify CMS of the change of ownership.

(i) This notice requirement applies to any national accrediting organization with CMS-approved accreditation program(s) that is the subject of a potential or actual change of ownership transaction, including accrediting organizations for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; Diabetic Self-Management Training (DSMT) entities, Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) suppliers, and clinical laboratories.

(ii) This notice must be provided to CMS in writing.

(iii) This notice must be provided to CMS no less than 90 days prior to the anticipated effective date of the change of ownership transaction.

(2) *Information submitted with the request for approval for change of ownership transaction.* The person(s) or organization(s) acquiring an existing CMS-approved accrediting organization or accreditation programs (that is, purchaser, buyer or transferee) through a change of ownership transaction must do the following:

(i) Seek approval from CMS for the purchase or transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership event; and

(ii) Meet the requirements of paragraphs (f)(2)(iii) through (f)(4) of this section to demonstrate that the entities that will be accredited with the transferred accrediting program(s) continue to meet or exceed the applicable Medicare conditions or requirements.

(iii) The following information must be submitted to CMS in the purchaser's/buyer's/transferee's request for approval of a transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change or ownership transaction:

(A) The legal name and address of the new owner;

(B) The three most recent audited financial statements of the organization that demonstrate the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities;

(C) A transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner, including:

(1) Changes to management and governance structures including current and proposed organizational charts;

(2) A list of the CMS-approved accreditation programs that will be transferred to the purchaser/buyer/transferee,

(3) Employee changes, if applicable,

(4) Anticipated timelines for action;

(5) Plans for notification to employees; and

(6) Any other relevant information that CMS finds necessary.

(3) *Written acknowledgements.* The purchaser/buyer/transferee must provide a written

acknowledgement to CMS, which states the following:

(i) If the application for the transfer of the existing CMS-approval for the accreditation program(s) to be transferred in the change of ownership transaction is approved by CMS, said purchaser/buyer/transferee must assume complete responsibility for the operations (that is, managerial, financial, and legal) of the CMS-approved accreditation programs transferred, immediately upon the finalization of the change of ownership transaction;

(ii) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the CMS imposed terms and conditions, to include program reviews and probationary status terms, currently approved by CMS; and

(iii) The purchaser/buyer/transferee must not operate the accreditation program(s) it acquired in the change in ownership transaction as CMS approved accreditation programs, until the effective date set forth within the notice of approval from CMS.

(iv) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the terms and conditions found at §§ 488.5 through 488.9

(4) *Notification.* The following written notifications are required after the change of ownership transaction has been approved by CMS:

(i) All parties to the change of ownership transaction must notify the providers and suppliers affected by such change within 15 calendar days after being notified of CMS's approval of the transfer of the existing CMS-approval for the accreditation programs to be transferred in the change of ownership transaction.

(ii) If applicable, the purchaser/buyer/transferee must acknowledge in writing to CMS that the accrediting organization or accreditation program(s) being acquired through a purchase or transfer of ownership was under a performance review or under probationary status at the time

the change of ownership notice was submitted.

(5) *Federal Register notice.* CMS will publish a notice of approval in the **Federal Register** of the transfer of the existing CMS approval for the accreditation program(s) to be transferred to the new owner, only after CMS receives written confirmation from the new owner that the change of ownership has taken place.

(6) *Notification to parties in the event that CMS does not approve the transfer of the existing CMS approval.* In the event that CMS does not approve the transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership transaction, CMS will notify all parties to the change of ownership transaction of such in writing.

(7) *Withdrawal of CMS approval for transferred accreditation programs due to failure to notify CMS of intent to transfer accreditation programs.* In the event that CMS was not made aware of or did not approve the transfer of the existing CMS-approval for the accreditation program(s) to be transferred under a change of ownership:

(i) The existing AO would be permitted to continue operating their existing CMS-approved accreditation programs, if the change of ownership transaction was not completed, unless our review of the transaction revealed issues with the AO that were the subject of the unfinalized change of ownership transaction that was previously unknown to CMS.

(ii) If a change of ownership transaction was completed without notice to CMS or the approval of CMS, CMS would be able to withdraw the existing approval of the AO's accreditation programs in accordance with § 488.8(c)(3)(ii) and (iii) of this section.

(8) *Withdrawal of CMS approval for accreditation programs which are transferred notwithstanding CMS' disapproval of the transfer.* In the event that the parties complete the change of ownership transaction, notwithstanding CMS disapproval and the

purchaser/buyer/transferee attempts to operate the transferred accreditation program(s) under the CMS-approval granted to the previous owner, CMS will withdraw the existing approval of the transferred accreditation program(s) in accordance with the procedures set out at § 488.8(c)(3)(ii) and (iii).

(9) Requirements for continuation of a deemed status accreditation of Medicare-certified providers and suppliers after CMS withdraws the existing approval of the transferred accreditation program(s). If CMS withdraws the existing approval of the transferred accreditation program(s) because the change of ownership transaction was completed without notice to CMS or the approval of CMS, an affected Medicare-Certified provider or supplier's deemed status will continue in effect for 180 calendar days if the Medicare-Certified provider or supplier takes the following steps set forth in § 488.8(g).

(i) The Medicare-certified provider or supplier must submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **FEDERAL REGISTER**; and

(ii) The Medicare-certified provider or supplier must provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe in accordance with § 488.8(g).

(iii) Failure to comply with the timeframe requirements specified in § 488.8(g) will place the provider or supplier under the SA's authority for continued participation in Medicare and on-going monitoring.

(10) Requirements for continuation of accreditation for non-certified suppliers when CMS withdraws the existing approval of the transferred accreditation program(s). If CMS withdraws its existing approval from a transferred non-certified accreditation program for

Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; Diabetic Self-Management Training (DSMT) entities; Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) suppliers; or clinical laboratories, because a change of ownership transaction was completed without notice to or the approval of CMS, such affected non-certified supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval, if such non-certified supplier take the steps specified paragraphs (f)(10)(i) and (ii) of this section --

(i) The non-certified supplier must submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**; and

(ii) The non-certified supplier must provide written notice to CMS stating that it has submitted an application for accreditation under another CMS-approved accreditation program within the 60-calendar days from the date of publication of the removal notice in the **Federal Register**.

(iii) Failure to comply with the above-stated timeframe requirements will result in de-recognition of such provider or supplier's accreditation.

11. Section 488.1030 is amended by adding paragraph (g) to read as follows:

§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.

* * * * *

(g) *Change of ownership.* An accrediting organization that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f).

PART 493- LABORATORY REQUIREMENTS

10. The authority citation for part 493 is revised to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16).

11. Section 493.553 is amended by adding paragraph (e) to read as follows:

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

* * * * *

(e) *Change of ownership.* An accrediting organization that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f) of this chapter.

Dated: November 7, 2018.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: April 2, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.